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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,551	08/07/2006	Stig Ollmar	P08984US01/BAS	8295

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EXAMINER

D'ANGELO, MICHAEL J

ART UNIT	PAPER NUMBER
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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,551	Applicant(s) OLLMAR ET AL.	
	Examiner MICHAEL D'ANGELO	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79,80,82,86-93 and 95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-80, 82, 86-93 and 95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/10/2010 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 2. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
3. Claims 79, 82, 91, and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963).

Regarding claim 79, Caduff discloses a system for measuring the impedance through subcutaneous tissue and correlating that impedance to a blood glucose level (column 2 lines 10-55) comprising an injection electrode and sensing electrode (electrodes 18 and 19) for injecting a current into the body and sensing the voltage caused by the current (column 2 lines 39-47), a means for measuring the impedance and processor for correlating the impedance with a relationship between the impedance

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and glucose level and for calculating the blood glucose level (column 7, lines 4-17), but fails to disclose the use of a pair of injection and sensing electrodes.

However, Bauer disclose a glucose measuring system that uses impedance as a measurement parameter based on the voltage applied between an injection and sensing electrode (column 12 line 50 to column 13 line 1), and further discloses that the sensing system (i.e. sensing and injection electrode) may be duplicated (i.e. multiplexed) (column 17, lines 58-62, the examiner notes that if multiple sensor strips are used there would be pairs of injection and sensing electrodes present).

4. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the electrode system of Caduff to include using pairs of injection and sensing electrodes as taught by Bauer in order to reduce the likelihood of false readings.

Regarding claim 82, Caduff discloses the tissue being blood vessels (column 1 lines 35-39)

Regarding claims 91 and 93, Caduff discloses the use of a visual display for indicating the calculated blood glucose (display 11)

5. Claims 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963) and further in view of Purvis et al. (US 2004/ 0182719).

6. **Regarding claims 86 and 87**, Caduff as modified by Bauer discloses a source of electrical current connected to the injection electrodes (VCO 1 of Caduff), and where the electrical current is provided at an array of frequencies between 1Hz and 10 MHz

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(column 4 lines 30-31 of Caduff), but fails to disclose an amperometer or a voltmeter, wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes.

7. However, Purvis discloses an amperometer and a voltmeter (paragraph 5, lines 9-11 and paragraph 12, lines 1-4), wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes (paragraph 5, lines 9-11 and paragraph 12, lines 1-4).

8. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Caduff, as modified by Bauer to include an amperometer and a voltmeter, wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes, as taught by Purvis, in order to control the voltage and sense the voltage/current.

9. Claims 80 and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963) and further in view of Steil et al. (US 2003/0130616).

Regarding claims 80, Caduff as modified by Bauer fails to disclose where at least one pair of electrodes is adapted for inserting into body tissue.

However, Steil discloses glucose monitoring electrodes located within the subcutaneous tissue (see figure 3).

10. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify an electrode configuration similar to that of Caduff as modified by

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Bauer to have the electrodes subcutaneously implanted in order to provide accurate conduction of the voltage through the patient tissue.

11. **Regarding claims 88-89 and 92**, Caduff as modified by Bauer fails to disclose that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level, a means for calibrating the apparatus against a directly measured glucose, or the apparatus is implanted in the body tissue for which the impedance is to be measured.

However, Steil discloses that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level (abstract, view figure 1, paragraph 98, lines 30-35), a means for calibrating the apparatus against a directly measured glucose level (paragraph 248, lines 1-8, view figure 32), and the apparatus is implanted in the body tissue for which the impedance is to be measured (paragraph 318, lines 1-4).

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Caduff as modified by Bauer to include that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level, a means for calibrating the apparatus against a directly measured glucose, and the apparatus is implanted in the body tissue for which the impedance is to be measured in order to provide a system that can easily notify the

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user of their glucose levels as well as provide a means for keeping the users glucose in a health range therefor increasing safety.

13. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963) and further in view of Abreu (US 2002/0049389).

14. **Regarding claim 90**, Caduff as modified by Bauer fails to disclose that the processor is programmed to determine the glucose level based on a principal component analysis and a partial least square regression analysis.

However, Abreu discloses a processor programmed to determine the glucose level based on a principal component analysis and a partial least square regression analysis (paragraph 296, lines 6-8, the examiner notes that although the disclosure of Abreu is not directed toward using skin impedance the use of principal component analysis and a partial least square regression taught by abreu can be applied to any physiological signal to reduce processing variability).

15. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Caduff, as modified by Bauer to determine the glucose level based on a principal component analysis and a partial least square regression analysis as taught by Abreu in order to reduce variability due to tissue structure.

16. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963) and further in view of Ollmar et al. (US 2003/0220581).

Regarding claim 95, Caduff as modified by Bauer fails to disclose an impedance depth between .1-2mm.

However, Ollmar discloses measuring impedance using the Scibase II (paragraph 112, the examiner notes that in the applicant's specification on page 11 lines 2-4 it is cited that the Scibase II is used to measure impedance at a depth range of 0.1-2 mm. Ollmar discloses using the Scibase II therefor it can be said to meet the limitation of the required depth).

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Caduff, as modified by Bauer to incorporate an impedance depth between .1-2mm as taught by Ollmar in order to provide a device that can vary the penetration depth, providing a more accurate system.

Response to Arguments

Applicant's arguments with respect to claim 79 have been considered but are moot in view of the new ground(s) of rejection. A new rejection incorporating Caduff and Bauer as shown above teach the use of a pair of injection and sensing electrodes for correlating impedance to blood glucose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-friday 9-5 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/M. D./
Examiner, Art Unit 3735